

REMARKS

Claims 1-9, 11-16, 18-24, 26, 27, and 29-31 were pending in the present application. Claims 1, 3, 19, 26, 29, and 31 are hereby amended. Claims 16 and 24 are hereby cancelled. Claims 32-34 are newly presented. After entry of this amendment, claims 1-19, 11-15, 18-23, 26, 27, and 29-34 remain pending in the present application.

Summary of Examiner Interview of March 2, 2009

Applicants thank the Examiner for the courtesy of the telephonic interview conducted on March 27, 2009, with the undersigned Applicants' representative. All pending claims were discussed, along with the Roller and Oswin references. Applicants' representative proposed amendments and remarks consistent with those presented herein.

Claim Rejections Under 35 USC §103

Claims 1-9, 11-13, 19-23, and 29-31 over Roller in view of Birks; AND Claims 14 and 16 over Roller in view of Birks further in view of Oswin

Claims 1-9, 11-13, 19-23, and 29-31 were rejected under 35 USC § 103(a) as being unpatentable over U.S. 7,192,782 (hereinafter "Roller") in view of US 7,045,359 (hereinafter "Birks").

Applicants note that independent claims 1, 19, and 31 have been amended to specify an electrochemical NO sensor. The remaining rejected claims depend from claims 1 or 19. Applicants assert that neither Roller et al. nor Birks et al. teach or suggest the use of an electrochemical sensor.

Applicants note that claims 16 and 24, which were specifically directed to an electrochemical sensor, were rejected over Roller in view of Birks and further in view of US 3,925,183 (hereinafter "Oswin"). Amended claims 1 and 19 essential re-present previous claims 16 and 24 in independent form, respectively. Accordingly, Applicants hereby address the patentability

of the rejected claims, 1-9, 11-13, 16, 19-23, 24, and 29-31 over Roller in view of Birks and further in view of Oswin.

With respect to Oswin, the Examiner referred to the Office Action of January 3, 2008, for the relevant teachings of Oswin. In that Office Action, the Examiner stated that Oswin teaches measurement of breath oxides using an electrochemical cell. The Examiner indicated that the Abstract of Oswin teaches that electrochemical cells are advantageous because they do not require additional heat input. Further, the Examiner finds that it would have been within the skill of the art to modify EP0904729 in view of Oswin to use an electrochemical cell to gain the above advantage. Applicants presume that the Examiner's reasoning remains the same, with respect to modifying Roller in view of Oswin. Applicants respectfully assert that it would not be obvious to modify Roller in view of Oswin.

Applicants assert that the Examiner's proposed modification of Roller to include an electrochemical sensor, in accordance with Oswin, would constitute an impermissible change of the principle of operation of Roller, and therefore cannot be the basis of a *prima facie* obviousness. See MPEP 2143.01(VI).

In the Background of the Invention, Roller teaches that prior art methods "require frequent calibration of the NO sensor using a calibration gas with a known NO concentration" and that "this requirement complicates use of such sensing technology." Roller at column 2, lines 11-14. To address this problem, Roller teaches a "method for comparing a level of a marker gas to a level of a calibration gas" wherein "the marker gas and the calibration gas are present in an exhaled breath sample." Roller at column 2, lines 29-32. Roller teaches the use of a spectrometric sensor allowing for the concurrent measurement of two different gases within the same breath sample. Roller at column 2, lines 3-17. In particular, Roller teaches measuring NO, without the need for calibration using a separate calibration gas, by referencing to CO₂ in the breath sample, which has a known concentration. Roller at column 7, lines 36-39.

Modifying Roller with Oswin to replace the spectrometric sensor with an electrochemical sensor would represent a change of the principle of operation of Roller. An electrochemical sensor would not be amenable to the internal calibration method enabled by a spectrometric sensor. Accordingly, the modified device of Roller would no longer be capable of calibration using CO₂, intrinsic to the exhaled breath sample. A modification that would disable and alter the principle of operation would not be obvious to one of skill. Rather, such a modification would only arise through hindsight. Applicants assert that the prohibition of MPEP 2143.01(VI) against modifications of a reference's principle of operation is intended to prevent such "hindsight bias." *Cf. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (U.S. 2007).

Further, Applicants respectfully assert that the rationale proposed by the Examiner for modification to an electrochemical sensor, the advantage of not requiring additional heat input, is technically incorrect and does not provide a rationale for modifying Roller to employ an electrochemical sensor. The advantage of not requiring additional heat input is not an intrinsic property of the electrochemical sensor. Rather, a "heat reservoir" (such as a quantity of wax heated by a car battery) is provided to heat the electrochemical sensor. Oswin at column 3, line 58, to column 4, line 6. Applicants respectfully assert that the Examiner has not articulated a rationale for the proposed modification of Roller to include an electrochemical sensor, in view of Oswin.

For the reasons stated above, Applicants request that the rejection under 35 USC § 103(a) over Roller in view of Birks and over Roller in view of Birks, and further in view of Oswin, be withdrawn.

Claims 14-15, 18, and 26-27 over Roller in view of Birks further in view of Holowko

Claim 14-15, 18 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roller et al. (U.S. Patent No.: 7,192,782) in view of Birks et al., as applied to claim 1-9, 11-13, 18-23 and 30-31 above, and further in view of US 6,039,251 (hereinafter "Holowko").

For the reasons stated above, Applicants request that the rejection under 35 USC § 103(a) over Roller in view of Birks, and further in view of Holowko, be withdrawn.

New Claims 32-34

New claims 32-34 are directed to a separate ambient air inlet connected to the NO scrubber. Claim 33 in particular is directed to a device in which the NO scrubber is configured to provide NO-free ambient air to the patient. Claim 34 in particular is directed to a device in which the NO scrubber is configured to provide NO-free ambient air directly to the sensor. Applicants note that Birks does not disclose an NO scrubber connected to a separate ambient air inlet. Rather, the NO scrubber of Birks is configured to scrub a portion of the exhaled gas sample. Birks at column 7, lines 27-34.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No.: 03-1952** referencing **Docket No.: 514862000700**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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